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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/596,444 | 06/19/2000 | Wei Huang | LJL 354B | 4000 |

7590 04/20/2004

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| EXAMINER | |
|---|---|
| LAM, ANN Y | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | |

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/596,444 | HUANG ET AL. | |
| | Examiner | Art Unit | |
| | Ann Y. Lam | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-10,12,17 and 47-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12,17 and 47-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5, 6, 21 and 24*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of the election requirement in the paper filed January 12, 2004 is acknowledged. The traversal is on the ground(s) that Examiner reduced the scope of claim 1 in formulating the restriction requirement, and that the 15 enumerated peptides share many common structural and/or biochemical properties such that they should be examined together (see page 8 of Applicant's response.) This is not found persuasive because the 15 different peptides listed in claim 16 are each species of the invention regardless of whether or not they are in the independent claim, and they are a burden on the Examiner in searching for each of the 15 different peptides.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 recites requires that the protein and the peptide are different. However, claim 6 depends on claim 1, which requires that the luminescence polarization of the luminescent peptide (as opposed to the protein) be measured. Thus, it is unclear how the phosphorylated protein in claim 6 is detected.

Claim 7 requires the step of "providing at least one phosphate group on the luminescent peptide" (line 2). Claim 7 depends on claim 1 and it is unclear whether or not this phosphorylation step is the same as the phosphorylation step in claim 1, lines 4 and 6-7.

Claim 7 also requires the step of "competing with the luminescent peptide by catalyzing formation of unlabelled phosphorylated protein" (lines 4-5.) It is unclear as to what is competing with the luminescent peptide, and it is unclear as to what is catalyzing formation of unlabelled phosphorylated protein.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 12, 17 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Sauvage et al., 6,022,708, in view of Schindele et al., 5,494,793.

De Sauvage discloses the invention substantially as claimed.

More specifically, de Sauvage discloses a method of detecting addition or removal of a phosphate group to or from a substrate (column 32, lines 56-58), comprising contacting a luminescent peptide (i.e., the "substrate", column 32, line 58) with a binding partner (i.e., "antibody", column 33, line 11) that binds specifically to the peptide only if the peptide is phosphorylated (column 33, lines 11-12), or only if the peptide is not phosphorylated, wherein the peptide is a substrate (i.e., "kinase substrate", column 32, line 53) for an enzyme that catalyzes addition or cleavage of a phosphate group to or from a protein (column 32, lines 53-55.)

However, de Sauvage does not teach that the binding partner includes an entrapped metal, nor does de Sauvage teach the step of measuring luminescence polarization from the luminescent peptide, wherein the amount of measured luminescence polarization can be related to the extent of binding between the luminescent peptide and the binding partner.

However, de Sauvage teaches that the measurement of the amount of substrate phosphorylated may be carried out by means of immunoassay, or other well-known methods (column 33, lines 6-16.)

Schindele teaches an immunoassay method wherein a phthalocyanine derivative is conjugated with, for example, an antigen or antibody (column 4, lines 19-20). For use as a fluorophore, the phthalocyanine may be metallated with for example, aluminum or

gallium (column 4, lines 33-35.) For use in immunoassay, the phthalocyanine derivative is conjugated either directly or indirectly to the antigen or antibody of interest (column 4, lines 56-59.) Schindele also teaches the step of measuring luminescence polarization from the luminescent peptide, wherein the amount of measured luminescence polarization can be related to the extent of binding between the luminescent peptide and the binding partner (column 12, lines 28-35.) The method greatly enhances the performance of phthalocyanine dyes are detectable markers in immunoassays (column 4, lines 28-29.)

It would have been obvious to provide the immunoassay method taught by Schindele as the immunoassay method used to measure the amount of substrate phosphorylated in the de Sauvage method, since the Schindele is a known immunoassay that is desirable for enhancing the performance of a detectable marker.

As to claim 9, Schindele also teaches that the binding partner (i.e., the antigen or antibody, column 4, lines 19-20) comprises a macromolecule that includes entrapped metal ions (column 4, lines 33-35.)

As to claims 10 and 50, Schindele also teaches that the metal ions comprise gallium (column 4, lines 33-35.)

As to claim 17, Schindele also teaches the step of illuminating the sample with polarized light (column 12, lines 28-35.)

As to the remaining claims, de Sauvage, also teaches the following.

As to claim 2, the kinase activity is determined (column 33, lines 23-24, de Sauvage.)

As to claim 3, phophatase activity is determined (column 29, line 54, and column 31, line 31, de Sauvage.)

As to claim 5, the protein and the peptide are the same (column 32, line 58, de Sauvage.)

As to claims 4, 8 and 12, de Sauvage teaches that a variety of peptides (i.e., substrates) may be used including synthetic peptide substrates (column 32, lines 63-64), and other substrates, which are superior by way of affinity for the kinase, minimal perturbation of reaction kinetics, etc. (column 32, line 66 – column 33, line 5.)

Thus, as to claim 4, it would have been obvious to use a peptide with fewer than about 15 amino acids so long as the peptide has a strong affinity for the kinase, or other desirable characteristics disclosed by de Sauvage.

As to claim 8, it would have been obvious to provide a binding partner that binds specifically to a phosphorylated protein substantially without regard to the particular amino acid sequence of the protein, so long as the peptide has a strong affinity for the kinase, or other desirable characteristics disclosed by de Sauvage.

As to claim 12, it would have been obvious to provide a peptide that is amidated on one end, so long as the peptide has a strong affinity for the kinase, or other desirable characteristics disclosed by de Sauvage.

As to claims 6 and 7, de Sauvage discloses that competitive binding assays may be used (column 28, lines 63-64.)

Claims 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Sauvage et al., 6,022,708, in view of Schindele et al., 5,494,793, as applied to claim 1 above, and further in view of Chaudiere et al., 5,861,262.

De Sauvage in view of Schindele discloses the invention substantially as claimed (see above), except for a stop solution including a chelator, and except for the steps of contacting and measuring being performed in a microplate well.

Chaudiere discloses a method of assaying enzymatic activity, including the step of adding a stop solution that includes a chelator (column 13, line 16-21; column 14, lines 34-36.) The assay in performed in a microplate well (column 13, lines 48-50.)

It would have been obvious to utilize a microplate well and to provide a stop solution as taught by Chaudiere in the de Sauvage method, as a known step in a method of assaying enzymatic activity.

## *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tchaga, 6,703,498, discloses a polymeric metal ion affinity compound for use in assays.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

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04/19/04